National Institute of Mental Health

Date: March 28, 2002

Subject: Request for SBIR Phase I Proposal under RFP No. NIMH-02-SBIR-PhaseI (formerly NIMH-02-DS-206X)

Dear Mr./Ms.:

The purpose of this Solicitation is to invite Phase I contract proposals from small business concerns that have the expertise to contribute to the mission of the NIMH. Included are instructions for the preparation of proposal, and a description of the proposal review process.

The NIMH invites you to submit a Phase I SBIR Proposal under the following topics:

Topic 0201 - Development of Dissemination and Implementation Tools for the Delivery of Empirically Validated Mental Health Interventions in Rural and Frontier Areas

Topic 0202 - Mental Health Intervention and Services Trial Operational Archive

Topic 0203 - Developing Research Based Training Modules for Conducting Community Based Mental Health Interventions and Services Research with Underserved Racial/Ethnic and Rural/Frontier Populations

Topic 0204 - Web-based Resource on Meeting the Mental Health needs of individuals with Neuropsychiatric and Neurodevelopmental Disorders

Topic 0205 - Evaluating Mental Health Interventions and Services Research Protocols in Urban and Rural Communities: Empirically Based Ethics Training Modules

The proposal must be submitted by May 28, 2002 at 4:00 PM, Eastern Time, and must be marked: SBIR Phase I Proposal. Please submit one (1) original and five (5) copies of your proposal and deliver the proposal to the following address:

<u>If hand-delivered or delivery service</u>

Contracts Management Branch
National Institute of Mental Health
Attn: Alex Navas, Contract Specialist
6001 Executive Blvd., Rm. 6107, MSC 9603
Rockville, MD 20852

<u>If using U.S. Postal Service</u>

Contracts Management Branch
National Institute of Mental Health
Attn: Alex Navas, Contract Specialist
6001 Executive Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603

This RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer (CO) is the only individual who can legally commit the Government to expenditure of public funds in connection with this proposed acquisition.

ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL(S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Any small business concern that intends to submit an SBIR proposal under this Solicitation should provide the Contracting Officer with early, written notice of its intent by completing the Proposal Intent Sheet in Attachment No. 1 of this Solicitation. If a topic is modified or canceled before this Solicitation closes, only those companies that have expressed such intent will be notified.

Questions about this requirement should be submitted (preferably via e-mail) to Alex Navas at anavas@mail.nih.gov, and marked "Offeror's Questions, Under FY2002 RFP No. NIMH-02-SBIR-PhaseI". These questions should be submitted by May 15, 2002. Mr. Alex Navas can also be contacted at 301-443-2696 or at fax 301-443-0501.

Sincerely,

David J. Eskenazi
Contracting Officer
Chief, Contracts Management Branch, ORM
National Institute of Mental Health, NIH

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The Appendices noted above are in Adobe Acrobat Reader fillable format.

SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS

I. GENERAL PROGRAM DESCRIPTION

The Small Business Innovation Research Program recently was reauthorized by the enactment of the Small Business Reauthorization Act of 2000, (Public Law 106-554. The Public Health Service (PHS), Department of Health and Human Services (HHS), and certain other Federal agencies must reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development (R/R&D) for a Small Business Innovation Research (SBIR) program. The objectives of the SBIR Program include stimulating technological innovation in the private sector, strengthening the role of small business in meeting Federal R/R&D needs, increasing private sector commercialization of innovations developed through Federal SBIR R&D, increasing small business participation in Federal R&D, and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program.

The SBIR program consists of three separate phases:

Phase I: Feasibility
$100,000
6 months

The objective of Phase I is to determine the scientific or technical feasibility and commercial merit of the proposed research or R&D efforts and the quality of performance of the small business concern, prior to providing further Federal support in Phase II. Phase I awards normally may not exceed $100,000 for direct costs, indirect costs, and profit (fixed fee) for a period normally not to exceed 6 months.

Phase II: Full R/R&D Effort
$750,000
2 years

The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Phase II awards normally may not exceed $750,000 for direct costs, indirect costs, and negotiated fees for a period normally not to exceed two years. That is, generally, a two-year Phase II project may not cost more than $750,000 for that project.

Phase III: Commercialization stage without SBIR funds

The objective of Phase III, where appropriate, is for the small business concern to pursue with non-Federal funds the commercialization objectives resulting from the results of the research or R&D funded in Phases I and II. In some Federal agencies, Phase III may involve follow-on, non-SBIR funded R&D or production contracts for products or processes intended for use by the U.S. Government.

SBIR PROGRAM ELIGIBILITY

Organizational Criteria: Each organization submitting a proposal under the SBIR program must qualify as a small business concern (defined in Section II.)

Access to special facilities or equipment in another organization is permitted (as in cases where the SBIR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project). However, *research space occupied by an SBIR contractor organization must be space that is available to and under the control of the SBIR contractor for the conduct of its portion of the project*. Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether or not such sharing constitutes control or the power to control.

Whenever a proposed SBIR project is to be conducted in facilities other than those of the offeror organization, a letter must be submitted *with* the proposal stating that leasing/rental arrangements have been negotiated for appropriate research space (i.e., space that will be available to and under the control of the SBIR contractor organization).

This letter must be signed by an *authorized official of the organization whose facilities are to be used for the SBIR project.* It also must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the offeror organization.

All SBIR contract proposals will be reviewed with the above considerations in mind. *If it appears that an offeror organization does not meet eligibility requirements, the NIMH will request a size determination of the organization from the cognizant Small Business Administration (SBA) regional office. The evaluation of the proposal for scientific merit will be deferred until the SBA provides a determination*.

Principal Investigator Criteria. The primary employment of the principal investigator must be with the offeror at the time of contract award and during the conduct of the proposed project. The principal investigator is the single individual designated in the contract proposal with responsibility for the scientific and technical direction of the project. Primary employment means that *more than one half of the principal investigator's time* is spent in the employ of the small business concern. *Primary employment with a small business concern precludes full-time employment at another organization*.

In the event that the principal investigator: (1) is a less-than-full-time employee of the small business, (2) is concurrently employed by another organization, or (3) gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position, at the time of submission of the proposal, *it is essential that documentation be submitted with the proposal to verify his/her eligibility*. If the principal investigator also is employed or appears to be employed by an organization other than the offeror organization (e.g., a university, a nonprofit research institute, or another company), a letter must be provided by the *non-offeror organization* confirming that the principal investigator will, if awarded an SBIR contract, become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the principal investigator is employed by a university, the Dean's Office must provide such a letter. If the principal investigator is employed by another for-profit organization, the corporate official must sign the letter. This documentation is required for every proposal that is submitted, even one that is a revision of a previously submitted proposal.

Performance Site Criteria. For both Phase I and Phase II, the research or R&D project activity *must be performed in its entirety in the United States (see Section III. Definitions)*.

Market Research. *The NIMH will not support any market research under its SBIR program*. Neither will it support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable. For purposes of the SBIR program, "market research" is the systematic gathering, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

II. DEFINITIONS

Clinical Research. NIH defines human clinical research as: **(1)** Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. **(2)** Epidemiologic and behavioral studies. **(3)** Outcomes research and health services research. Note: Studies falling under Exemption

4 for human subjects research are not considered clinical research by this definition.

Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others); as used here, commercialization includes both government and private sector markets.

Contract. An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when: (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Innovation. Something new or improved, including research for: (1) development for new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For purposes of this solicitation, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

Key Personnel Engaged on Project. This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Prototype. A model of something to be further developed that includes designs, protocols, questionnaires, software, devices, etc.

Research or Research and Development (R/R&D). Any activity that is:

1. A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.
2. A systematic study directed specifically toward applying new knowledge to meet a recognized need.
3. A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Small Business Concern. A small business concern is one that, at the time of award of Phase I, meets all of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit;
2. Is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens;
3. Has, including its affiliates, a *number of employees not exceeding 500*, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, *et seq.,* are affiliates of one another when either directly or indirectly:
   a. One concern controls or has the power to control the other; or
   b. A third party or parties controls or has the power to control both.

   Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t). *Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative*.

Joint Ventures or Limited Partnerships. Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern as defined in this Solicitation.

Socially and Economically Disadvantaged Individual. A member of any of the following groups:

- Black Americans
- Hispanic Americans
- Native Americans
- Asian-Pacific Americans
- Subcontinent Asian Americans
- Other groups designated from time to time by SBA to be socially disadvantaged
- Any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act,15 U.S.C. 637(a)

Socially and Economically Disadvantaged Small Business Concern. A socially and economically disadvantaged small business concern:

1. Is one that is at least 51 percent owned by: (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; and
2. Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, the territories and possessions of the U.S., the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

Woman-Owned Small Business Concern. A small business concern that is at least 51 percent owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

III. PHASE I PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

A. LIMITATIONS ON LENGTH OF PROPOSAL

SBIR Phase I proposals shall not exceed a total of *25 single-spaced pages*, including Appendix A, B, and C. *Pages should be of* standard size (8 l/2" X 11*"),* and the font should be no smaller than 10-point. *Excluded* from the 25-page limitation are cover letters, letters of commitment from collaborators and consultants (and any letters to determine eligibility). Unless specifically solicited by a Contracting Officer, no other appendices may be submitted, and if submitted, they will not be considered in the evaluation of scientific and technical merit.

B. PROPOSAL COVER SHEET

Complete the form identified as Appendix A and use it as the first page of the proposal. *No other cover sheet should be used*.

- ***Topic Number.*** Provide the appropriate numerical designator of the research topic
- ***Project Title.*** Select a title that reflects the substance of the project. Do not use the title of the topic that appears in the Solicitation.

C. ABSTRACT OF RESEARCH PLAN

Complete the form identified as Appendix B, and insert it as the second page of each proposal. Abstracts of successful proposals will be published by NIMH and, therefore, should not contain proprietary information. The abstract should include a brief description of the problem or opportunity, specific aims, and a description of the effort. Summarize anticipated results and potential commercial applications of the proposed research.

D. RESEARCH PLAN

Any research proposal involving the collection of information, such as surveys or interviews, of more than nine respondents will require clearance by the U.S. Office of Management and Budget. Therefore, it is not practical to propose such an activity for Phase I, which normally has only a six-month duration.

Beginning on page three of the proposal, discuss in the order indicated the following elements:

1. ***Identification and Significance of the Problem or Opportunity.*** Provide a clear statement of the specific technical problem or opportunity addressed.

2. ***Technical Objectives.*** State the specific objectives of the Phase I effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3. ***Work Plan.*** Provide a detailed plan for the R&D to be carried out, including the experimental design, procedures, and protocols to be used. Address the objectives and the questions stated in *Item 2* above. Discuss in detail the methods to be used to achieve each objective or task.

4. ***Related Research or R&D.*** Describe significant research or R&D that is directly related to the proposal, including any conducted by the principal investigator/project manager or by the proposing firm. Describe how it relates to the proposed effort and any planned coordination with outside sources.

5. ***Relationship with Future R&D.***

   a. State the results expected from the proposed approach.

   b. Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

6. ***Potential Commercial Applications.*** Describe why the proposed project appears to have potential commercial applications, and whether and by what means the proposed project appears to have potential use by the Federal Government.

7. ***Key Personnel and Curriculum Vitae (CV).*** Identify key personnel, including their directly related education, experience, and bibliographic information. Where vitae are extensive, focus on summaries of the most relevant experience or publications. *Provide dates and places of employment* and some information about the nature of each position or professional experience. Curriculum vitae must identify the current or most recent position.

8. ***Salary Rate Limitation.*** Beginning with the HHS Appropriations Act of Fiscal Year (FY) 1990, direct salary rate limitations have been placed on the NIH contracts that support the NIH Extramural R&D activities. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses. The FY 2002 HHS Appropriations Act limited the direct salary rate using FY 2002 funds to Executive Level II, which is currently $166,700 per year.

9. ***Consultants.*** Involvement of consultants is strongly encouraged. Such use must be described in detail and supported by appropriate letters from each individual confirming his/her role in the project.

10. ***Facilities and Equipment.*** Indicate where the proposed research will be conducted. *One of the performance sites must be the offeror organization*. Describe the facilities to be used; identify the location; and briefly indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Include clinical, computer, and office facilities of the offeror and those of any other performance sites to be used in the project.

    List the most important equipment items already available for this project, noting location and pertinent capabilities of each.

    Any equipment and products purchased with Government funds shall be American-made, to the extent possible.

    Title to Equipment. Title to equipment purchased with Government funding by the SBIR awardee in relation to project performance vests upon acquisition in the Federal Government. However, the Government may transfer such title to an SBIR awardee upon expiration of the project where the transfer would be more cost-effective than recovery of the property.

E. CURRENT AWARDS AND PENDING PROPOSALS/APPLICATIONS

A small business concern may not submit both a contract proposal and a grant application for essentially the same project. The only exception would be the submission of a grant application after a contract proposal has been evaluated and is no longer being considered for award.

While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work (as defined in this Solicitation) for consideration under numerous Federal program solicitations, it is unlawful to enter into contracts or grants requiring essentially equivalent effort.

If a firm elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other Federal program solicitations, include a statement in each such proposal indicating the information requested in items 1-10 set forth below.

In addition, provide the information requested in items 1-10 on (a) active funding through contracts, grants, and cooperative agreements from public or private sponsors; (b) contract proposals and grant and cooperative agreement applications pending review or funding; and (c) contract proposals and grant and cooperative agreement applications about to be submitted.

1. Name and address of the funding source.
2. Type of award (contract, grant, cooperative agreement) and identifying number.
3. Title of research project.
4. Name and title of principal investigator or project manager.
5. Hours per week on the project by the principal investigator or project manager.
6. Annual costs proposed or awarded.
7. Entire period of support.
8. Date of proposal/application submission or date of award.
9. Title, number, and date of solicitations under which proposals or applications were submitted or awards received.
10. The specific applicable research topic for each SBIR proposal or application submitted or award received. *Specifically identify those projects that are SBIR*.

F. PROPOSED COST BREAKDOWN

Complete the form identified as Appendix C (Contract Pricing Proposal). A blank sheet of paper can be substituted for page 2 of the appendix if it addresses all items on page 2. Page 3 of Appendix C, General Information, should not be included with the proposal. The cost breakdown should appear as the last section of the proposal. *If some items on this form do not apply to the proposed project, they need not be completed*.

- Under "Government Solicitation No.," enter -02-SBIR-PhaseI."
- If supplies are proposed, provide the quantities and the price per unit.
- Under "Direct Labor," *list all key personnel by name*. Support personnel may be consolidated into categories or labor classes, e.g., research assistants or data processing clerks.
- If travel is proposed, provide the following details on "Exhibit A – Supporting Schedule": destination(s); duration of trip(s); number of travelers; and cost per trip, broken down by cost elements, e.g., airfare, lodging, and meals.
- If consultants are proposed, provide name(s), rate(s), and number of hours/days.
- If a subcontract is proposed, provide the same type of detailed cost breakdown as required for Appendix C. *Also provide a letter of commitment from the subcontractor.*
- Use "Exhibit A – Supporting Schedule" (page 2 of Appendix C, or a blank sheet of paper) to itemize and justify all major cost elements.

G. JUST IN TIME PROCEDURES

The NIH has initiated special *"just in time" procedures* that are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals.

The following are among the documentation that may be part of the "just in time" procedures:

- **Data Universal Numbering System (DUNS) number.** A DUNS number may be obtained immediately, at no charge, by calling Dun and Bradstreet on (800) 333-0505.
- ***Travel Policy.*** The offeror's written travel policy
- ***Annual Financial Report.*** The offeror's most recent annual financial report and or an annual audit report.
- ***Total Compensation Plan.*** Salary and fringe benefits of professional employees under service contracts.
- ***Data Substantiating the Costs and Prices Proposed.*** That is, payroll documentation, vendor quotes, invoice prices, etc.
- **Submission of Electronic Funds Transfer Information (EFT) -** submission of this information satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration.
- ***Representation and Certifications*** **–** Negotiated Contract, only one completed and signed copy.
- ***Indirect Rates*** – explain the components of proposed rates. Indicate if rates have been negotiated with a federal agency or if they are based on an audit. A copy of the rate agreement with a federal agency or the audit report may be requested under "just in time".
- ***Payroll sheets*** – or other evidence to support proposed labor rates. Include information regarding organizational policies for the review of salaries and the granting of increases. For proposed consultants include evidence that consultants receive the hourly/daily rate from other federal agencies, or from other organizations for similar work.
- ***Certify*** – that the offeror has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

H. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH requires education on the protection of human research participants for all individuals identified as "key personnel" before funds are awarded for contract proposals involving human subjects. For information relating to this requirement, see the following notice (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html), which was published June 5, 2000 in the *NIH Guide for Grants and Contracts*. Prior to award, the selected contractor will be required to provide a description of education completed in the protection of human subjects for all key personnel. While NIH does not endorse programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See http://ohsr.od.nih.gov/ for computer-based training developed for NIH that can be downloaded at no charge and modified for use. For information on facilitating education and developing curricula, see http://www.nih.gov/sigs/bioethics.

I. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

It is NIH policy that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects (see http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html) unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

Exclusion under other circumstances may be based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed

study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of the proposed outreach programs for recruiting women and minorities as participants.

All research projects involving human subjects are subject to the policy, whether or not they are exempt from human subject protections and Institutional Review Board (IRB) review requirements. All investigators proposing research involving human subjects should read the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research", which was published in the *NIH Guide for Grants and Contracts (October 9, 2001)*

J. INCLUSION OF CHILDREN IN RESEARCH INVOLVING HUMAN SUBJECTS

It is NIH policy that children must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them.

For purposes of this policy, a "child" is defined as an individual under the age of 21 years. Contracts involving human subjects include categories that would otherwise be exempt from the HHS regulations for the Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations, whether or not such research is otherwise exempt from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." Provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects," which was published in the *NIH Guide for Grants and Contracts* on March 6, 1998, and is available at http://grants.nih.gov/grants/guide/notice-files/not98-024.html

K. REQUIREMENT FOR ADEQUATE ASSURANCE OF PROTECTION OF HUMAN SUBJECTS

The HHS regulations for the Protection of Human Subjects, 45 CFR 46 (as amended), provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The requirement is that an approved assurance of compliance with the regulations must be on file with the Office for Human Research Protections (OHRP), DHHS (formerly Office for Protection from Research Risks (OPRR), NIH) before an HHS award can be made.

Neither an Institutional Review Board (IRB) review nor an OHRP-approved Assurance is required at the time the proposal is submitted or at the time that the proposals are peer reviewed.

The review group will consider carefully whether the proposal includes necessary safeguards to protect the rights and welfare of research participants. *No contract award can be made without IRB approval.* Therefore, following NIH peer review and notification of an Institute's decision to proceed with negotiations and funding, the offeror should proceed with IRB review. On request of the awarding component, OHRP will contact the offeror to provide detailed instructions for filing the necessary documents to request a Single Project Assurance (SPA).

The regulations define a "human subject" as a "living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually

identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46 (as amended).

In doubtful cases, prior consultation with the Office for Human Research Protections (OHRP), DHHS, (301) 496-7041, may be of assistance.

Inappropriate designations of the non-involvement of human subjects in an SBIR project may result in delays in the review of a proposal. The OHRP, on behalf of HHS, will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal.

Any SBIR contract involving human subjects that is awarded as a result of a proposal submitted in response to this Solicitation will include the following clauses:

1. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 (as amended) and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), DHHS. The Contractor further agrees to provide certification at least annually that the institutional review board has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR Part 46 (as amended) and the Assurance of Compliance.

2. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

3. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, DHHS, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

   If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OHRP, DHHS, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Health and Human Services Human Subject Assurances.

L. NEEDLE EXCHANGE

It is anticipated that the HHS Fiscal Year 2002 Appropriations Act will continue a restriction on using contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

M. BAN ON HUMAN EMBRYO RESEARCH

It is anticipated that the HHS Fiscal Year 2002 Appropriations Act will continue the ban on funding of human embryo research. Currently, contract funds may not be used for: (1) the creation of a human embryo or embryos for research purposes, or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that

is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Additionally, Federal funds may not be used for cloning of human beings.

N. RESEARCH USING HUMAN PLURIPOTENT STEM CELLS

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research using human pluripotent stem cells is proposed, the applicant organization will be in compliance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells published in the Federal Register http://www.nih.gov/news/stemcell/stemcellguidelines.htm

O. REQUIREMENT FOR ADEQUATE ASSURANCE OF COMPLIANCE WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

The PHS Policy on Humane Care and Use of Laboratory Animal (Policy) establishes a number of requirements in research activities involving live, vertebrate animals. It stipulates that an offeror organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. The PHS Policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes." An offeror organization proposing to use animals in PHS-supported activities must file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), NIH. When an offeror proposes research that involves animals, but the offeror does not have an Animal Welfare Assurance on file with OLAW, on request of the awarding component, OLAW will contact the offeror and provide detailed instructions for filing the necessary document.

Neither an Institutional Animal Care and Use Committee (IACUC) nor an OLAW-approved Assurance is required at the time the proposal is submitted.

Institutions having an Assurance with OLAW are encouraged to have an IACUC review before submitting the proposal and should furnish verification of IACUC approval with the proposal. However, an Assured organization may submit the verification of IACUC review after proposal submission but before the Initial Technical Review is initiated. If verification is not received before the Initial Technical Review meeting, the awarding component will not allow the review of the proposal.

No award for research involving animals will be made unless the offeror organization is operating in accord with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with PHS Policy. 48 CFR Part PHS 352 requires that any contract involving live, vertebrate animals, awarded as a result of a proposal submitted in response to this Solicitation include the following clauses:

1. Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.
2. The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
3. The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 *et seq.* and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.
4. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW),

National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Public Health Service Animal Welfare Assurances.

The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program, may be obtained by contacting:

Animal Care Staff
USDA/APHIS
4700 River Road, Unit 84
Riverdale, MD 20737
(301) 734-4980

Offerors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance.

Offerors are encouraged to visit the OLAW website at http://grants1.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

IV. INSTRUCTIONS FOR PROPOSAL SUBMISSION

Any proposal received after the exact time specified in the cover letter will not be considered unless it is received before award is made and:

1. It was sent by registered or certified mail not later than the fifth calendar day prior to the date specified for receipt of proposals;
2. It was sent by mail or hand-delivered and it is determined by the Government that the late receipt was due primarily to mishandling by the Government after receipt at the Government installation;
3. It was transmitted through an electronic commerce method authorized by the Contracting Officer and was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals;
4. It is the only proposal received, or;
5. It is received in the office designated for receipt of proposals on the first workday on which normal Government processes are resumed following an emergency or anticipated event that interrupts normal Government processes so that proposals cannot be received by the exact time specified in the Solicitation.

Despite the specified receipt date above, a proposal received after that date may be considered if it offers significant costs or technical advantages to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

V. METHOD OF SELECTION AND EVALUATION CRITERIA

A. EVALUATION PROCESS

Contract proposals are subjected to peer review by panels of scientists selected for their competence in relevant scientific and technical fields. The peer review panel will be responsible for evaluating proposals for scientific and technical merit. The peer review panel provides a rating, makes specific recommendations related to the scope, direction and/or conduct of the proposed research, and may provide a commentary about the funding level, labor mix and duration of the proposed contract project. The NIMH will also review the proposals. The

comments as well as those of the peer review panel will be presented during the negotiation/discussion phase of the award process.

Recommendations of the peer review panel and program staff are based on judgments about not only the technical merit of the proposed research but also its relevance and potential contributions to the mission and programs of the awarding component. A Phase I contract may be awarded only if the corresponding proposal has been recommended as technically acceptable by the peer review panel. ***Funding for any/all acceptable proposals is not guaranteed.***

B. TECHNICAL EVALUATION CRITERIA

In considering the technical merit of each proposal, the following factors will be assessed:

CRITERIA FOR PHASE I PROPOSALS	WEIGHT
1. The soundness and technical merit of the proposed approach and identification of clear measurable goals (milestones) to be achieved during Phase I.	40
2. The qualifications of the proposed principal investigator, supporting staff, and consultants.	20
3. The potential of the proposed research for technological innovation.	15
4. The potential of the proposed research for commercial application.	15
5. The adequacy and suitability of the facilities and research environment.	10

C. PROPOSAL DEBRIEFING

Offerors will be notified when they are no longer being considered for award. Offerors are entitled to a debriefing in accordance to FAR Subpart 15.5, which can be requested within three days of the receipt of the notification.

D. AWARD DECISIONS

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors in order of importance are:

Ratings resulting from the scientific/ technical evaluation process;

Areas of high program relevance;

Program balance (i.e., balance among areas of research); and

Availability of funds.

Although technical factors are of paramount consideration in the award of a contract, cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The NIMH is not under any obligation to fund any proposal or make any specific number of contract awards in a given research topic area. The NIMH may also elect to fund several or none of the proposals received within a given topic area. The SBIR contract projects do not require establishing a competitive range or requesting final proposal revisions before reaching source selection decisions.

VI. CONSIDERATIONS

A. AWARDS

1. The award instrument will be a contract.
2. A profit or fixed fee may be included in the proposal and the fee will be negotiated. A profit or fee is considered any amount in excess of actual direct and indirect cost incurred in the conduct of a project.
3. Phase I awards normally may not exceed $100,000 for direct costs, indirect costs, and profit (fixed fee) for a period normally not to exceed 6 months.

B. FINAL REPORT

Original plus 2 copies

A final report is required of all Phase I contractors. It should include a detailed description of the project objectives, the activities that were carried out, and the results obtained. An original and two copies of this report must be submitted as directed by the Contracting Officer not later than the expiration date of the Phase I contract.

C. PAYMENT

The Government may make payments, including invoice and contract financing payments, by electronic funds transfer (EFT). As a condition to any payment, the contractor is required to provide information required to make payment by EFT. This information, if needed, may be requested under "just in time" procedures.

D. LIMITED RIGHTS INFORMATION AND DATA

Proprietary Information. Information contained in unsuccessful proposals will remain the property of the offeror. The Government, however, may retain copies of all proposals. Public release of information in any proposal will be subject to existing statutory and regulatory requirements.

The Department of Health and Human Services (HHS) recognizes that, in responding to this Solicitation, offerors may submit information that they do not want used or disclosed for any purpose other than for evaluation. Such data might include trade secrets, technical data, and business data (such as commercial information, financial information, and cost and pricing data). The use or disclosure of such information may be restricted if offerors identify it and the Freedom of Information Act (FOIA) does not require its release. For information to be protected, offerors must identify in the Notice of Proprietary Information (on the Proposal Cover Sheet) the page(s) on which such information appears. Any other Notice may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure.

Unless disclosure is required by the FOIA, as determined by FOI officials of the HHS, data contained in those portions of a proposal that have been identified as containing restricted information, in accordance with the Notice of Proprietary Information, shall not be used or disclosed except for evaluation purposes.

The HHS may not be able to withhold data that has been requested pursuant to the FOIA, and the HHS FOI officials must make that determination. The Government is not liable for disclosure if the HHS has determined that disclosure is required by the FOIA.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of a proposal, the Government shall have the right to use or disclose the data to the extent provided by law. Proposals not resulting in a contract remain subject to the FOIA.

Rights to Data Developed Under SBIR Funding Agreement. Rights to data, including software developed under the terms of any funding agreement resulting from a contract proposal submitted in response to this Solicitation, shall remain with the awardee. However, the Government shall have the limited right to use such data for internal Government purposes and shall not release such data outside the Government without permission of the awardee for a period of four years from completion of each phase of the project under which the data was generated.

Copyrights. The awardee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with NIMH support. The awarding component receives a royalty-free license for the Federal Government and requires that each publication contain an acknowledgement of agency support and disclaimer statement, as appropriate. An acknowledgement shall be to the effect that: "This publication was made possible by contract number _____ from (NIMH)" or "The project described was supported by contract number _____ from (NIMH)."

Patents. Small business concerns normally retain the principal worldwide patent rights to any invention developed with Government support. Under existing regulations, 37 CFR 401, the Government receives a royalty-free license for Federal Government use, reserves

the right to require the patent-holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period to allow the awardee a reasonable time to file a patent application, nor will the Government release any information that is part of that application.

Inventions must be reported promptly—within two months of the inventor's initial report to the contractor organization—to the Division of Extramural Inventions and Technology Resources, NIH, at the address above. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

The reporting of inventions can be accomplished by submitting paper documentation, including fax, or electronically through the NIH Edison Invention Reporting System. Use of the Edison system satisfies all mandated invention reporting requirements and access to the system is through a secure interactive Web site http://www.iedison.gov to ensure that all information submitted is protected. In addition to fulfilling reporting requirements, Edison notifies the user of future time sensitive deadlines with enough lead-time to avoid the possibility of loss of patent rights due to administrative oversight. Edison can accommodate the invention reporting need of all organizations. For additional information about this invention reporting and tracking system, visit the Edison home page cited above or contact Edison via e-mail at Edison@od.nih.gov.

Sharing Biomedical Research Resources. It is the policy of the NIH that unique research resources developed with NIH funding must be shared with the research community. Restricted availability of these resources can impede the advancement of research. Principles and Guidelines for Recipients of NIH Research Grants and Contracts, as published in the Federal Register Notice on December 23, 1999 [http://ott.od.nih.gov/NewPages/RTguide_final.html], provide assistance to determine reasonable terms and conditions for acquiring and disseminating research tools, consistent with the objectives of furthering biomedical research and adhering to the Bayh-Dole Act.

Royalties. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1. Name and address of licensor.
2. Date of license agreement.
3. Patent numbers.
4. Patent application serial numbers, or other basis on which the royalty is payable.
5. Brief description (including any part or model number of each contract item or component on which the royalty is payable.)
6. Percentage or dollar rate of royalty per unit.
7. Unit price of contract item.
8. Number of units.
9. Total dollar amount of royalties.
10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37.)

E. PERFORMANCE OF RESEARCH AND ANALYTICAL WORK

In Phase I projects, two-thirds or 67% of the research or analytical effort must be performed by the small business concern, i.e., subcontracts for portions of the scientific/technical effort and consultant fees should not exceed 33% of the total cost breakdown.

Contract Clauses. Upon entering into a contract, the contractor agrees, in accordance with the terms and conditions of the contract, to accept certain legal commitments embodied in the clauses of Phase I contracts. The general clauses and provisions located in the file "General Clauses" at URL:

http://amb.nci.nih.gov/clauses/clauses.html apply to an SBIR Phase I Fixed-Price Research & Development Contract.

The following list illustrates the types of clauses to which a contractor is bound.

Clauses That Apply to Contracts *NOT* Exceeding $100,000

1. ***Standards of Work.*** Work performed under the contract must conform to high professional standards.
2. ***Inspection.*** Work performed under the contract is subject to Government inspection and evaluation at all times.
3. ***Termination for Convenience.*** The Government may terminate the contract at any time for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.
4. ***Disputes.*** Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the contracting officer with right of appeal.
5. ***Equal Opportunity.*** The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.
6. ***Affirmative Action for Veterans.*** The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.
7. ***Affirmative Action for Handicapped.*** The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.
8. ***Gratuities.*** The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.
9. ***American-made Equipment and Products.*** When purchasing equipment or products under an SBIR contract award, the contractor shall purchase only American-made items whenever possible.

Clauses That Apply to Contracts Exceeding $100,000

In addition to the foregoing clauses, the following clauses apply to contracts expected to exceed $100,000.

10. ***Examination of Records.*** The Comptroller General (or a duly authorized representative) shall have the right to examine any directly pertinent records of the contractor involving transactions related to this contract.
11. ***Default.*** The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.
12. ***Contract Work Hours.*** The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).
13. ***Covenant Against Contingent Fees.*** No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.
14. ***Patent Infringement.*** The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

F. ADDITIONAL INFORMATION

1. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR contract, the terms of the contract are controlling.
2. The Government is not responsible for any expenditures of the offeror in advance and in anticipation of an award.

VII. RESEARCH TOPICS

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to diminish the burden of

mental illness through research. To achieve this goal, the NIMH funds basic research, clinical studies, and services delivery research concerning any aspect of behavioral and mental disorders (including HIV prevention and neuro AIDS research). Ultimately, this research will lead to greater understanding, better treatment and rehabilitation or prevention of mental disorders. The NIMH is also concerned with the speedy dissemination and use of this knowledge through scientific communications and public education, and in its more effective implementation in practice and service delivery systems.

This solicitation invites proposals in the following areas:

0201 Development of Dissemination and Implementation Tools for the Delivery of Empirically Validated Mental Health Interventions in Rural and Frontier Areas

The purpose of this SBIR contract is to develop a plan for the dissemination and implementation of empirically validated interventions, services, and delivery-modes that have been adapted for use by mental health providers in rural and frontier areas. Particular emphasis is on the delivery of care that recognizes the unique service delivery and ethical dilemmas faced by small community mental health clinicians. This initiative is in response to recommendations put forth at the NIMH Conference on Rural Mental Health Research: Charting A Future Course.

The nearly 60 million Americans living in rural and frontier America have the same kinds of mental and general health problems as individuals who live in urban and suburban areas. However, the unique characteristics of such areas present additional barriers to mental health treatment and further limit receipt of appropriate services. These characteristics include widespread poverty, and fewer or more distant services that are made even less accessible by poor road conditions and limited public transportation. Other barriers may be culturally related to the extent that rural America still reflects a different set of values and lifestyles than urban America. There are language barriers for those who cannot speak or read English and physical obstacles for those with disabilities. In addition, the stigma of mental illness along with the lack of confidentiality and anonymity in small-towns often prevent many residents in need of care from seeking services. Mental health providers must address these barriers to provide effective and appropriate mental health services in rural and frontier communities.

Studies of effectiveness of interventions are typically first conducted in urban or suburban areas where the density and proximity of the population facilitate subject recruitment and expedite study completion. Building from the existing body of research documenting rural mental health needs, such intervention programs have begun to be adapted for effective delivery in rural settings. In addition, research on rural-adapted delivery modes such as telemedicine, computer-based interventions, telephone-based interventions and other technology-based tools is empirically documenting the utility of these approaches. A substantial amount of this research has been published from investigators at the Center for Rural Mental Health Services Research at the University of Arkansas, the University of New Mexico, the University of Colorado, Wake Forest and the University of North Dakota.

As emerging scientific research on rural-adapted interventions, services, and innovative delivery modes is becoming available, there is a critical need for development of tools to facilitate the dissemination and implementation of these to service providers in rural and frontier areas. The task of this SBIR contract is to develop an empirically-based plan for dissemination and implementation of rural and frontier mental health programs that incorporates: 1) appropriate, effective rural-adapted mental health services and interventions (e.g., teacher-focused; parent-focused); 2) a plan to ensure these interventions are implemented with fidelity (develop training tools, such as videos, training approaches); 3) determining a cost-effective approach to evaluating the implemented programs; 4) developing preliminary strategies for sustaining programs that are effective. The proposals should include pilot-testing this plan in a limited number of rural and frontier settings.

0202 Mental Health Intervention and Services Trial Operational Archive

The purpose of this contract is to develop an archive of operational experience in larger-scale, particularly multi-site, intervention (including services interventions) trials in mental health. As the field moves to larger, longer, more complex studies, it seems as though a set of

issues needs to be independently discovered and solutions need to be independently invented each time a study is begun. Examples of these issues include:

Structural: how should trials be organized; what functions should be centralized; what committees need to be established; how are disputes resolved; who has rights to data and when; should the data be archived for public use and when; by whom and how should strategies, committees, boards etc be reviewed and kept or discarded.

Operational: how are raters trained, reliability established and maintained; are there manuals and training tapes available and how should they be used; are the newer web-based approaches usable; how is site variability minimized; how is consent maintained over the long term; what are special operational challenges in non-academic settings particularly in relationship to issues of fidelity; what are the roles of community/consumer boards and how best can input from community be operationalized within ongoing research designs and; how is recruitment and retention monitored and maintained.

Practical: how should data safety and monitoring be carried out; what standard for conflicts of interest should be established; what incentives can be provided to sites and investigators for participation; should industry participation be invited; how to handle trial completion, open continuation, compassionate use; how should community involvement be established and maintained.

The contract would be to establish a plan for this archive in terms of content, approaches to investigators, database acquisition, storage and retrieval, and a system for access, sharing , and distribution. (including print or e-based journals). During Phase I applications can focus on interventions (treatment, rehabilitation, prevention) and/or services and can further focus on child and adolescent, adult or geriatric age groups.

The need for this activity was expressed by participants at various NIMH sponsored workshops such as the "Neurocognitive Outcome Measures in 21st Century Clincial Trials: Advancing the Translation of Cognitive Neuroscience" held in Bethesda on June 25-26 , 2001 and the "Dissemination and Implementation in Children's Mental Health Services" held in Bethesda on January 22-23, 2002.

0203 Developing Research Based Training Modules for Conducting Community Based Mental Health Interventions and Services Research with Underserved Racial/Ethnic and Rural/Frontier Populations

BACKGROUND

NIMH supported research on treatment, prevention and services for persons with or at high risk for mental disorders is increasingly conducted in "real world" settings and has highlighted the issues of health disparities and gaps in meaningful community participation in the conduct of such research. (See- Social and Cultural Dimensions of Health Program Announcement: http://grants.nih.gov/grants/guide/pa-files/PA-02-043.html, Patient Centered Care Program Announcement: http://grants.nih.gov/grants/guide/pa-files/PA-01-124.html, Research on Mental Disorders in Rural and Frontier Populations: http://grants.nih.gov/grants/guide/pa-files/PA-00-082.html) Several recent reports (NIMH Strategic Plan for Reducing Health Disparities: http://www.nimh.nih.gov/strategic/strategicdisparity.cfm; Bridging Science and Service Report: http://www.nimh.nih.gov/research/bridge.htm) have emphasized the pressing need- in terms of equity, science, and public health- for studies to include samples of traditionally underserved racial/ethnic and rural/frontier populations. In fact, many salient questions regarding the efficacy, effectiveness and diffusion of mental health interventions and services can only be addressed within an appropriate community context.

University based researchers and their community partners often begin de novo in initiating, establishing, sustaining, evolving and evaluating their partnerships. Frequent barriers to that process include lack of effective two-way communication and lack of time and personnel dedicated to the collaborative process. The productivity and frequency of such research partnerships can be enhanced by empirically based resources to aid in the scientific, practical and operational aspects of conducting mental health community based interventions and services research with underserved racial/ethnic and rural/frontier populations.

Increasing participation in mental health research by underserved groups is necessary to achieve not only better mental health outcomes but to establish empirically validated services and interventions for various communities and enhance the dissemination and implementation these. Achieving broader participation will require wider community outreach, and mutual understanding and goal setting between researchers and underserved populations. This announcement is intended to contribute to the reduction of health disparities by enabling NIMH to build a stronger portfolio of research relevant to the identified historically underserved populations.

PURPOSE

Achieving the goal of community participation in research requires researchers, institutions, and racial/ethnic and rural/frontier communities to work together in new and different ways. Thus, there is a need for the development, dissemination, and implementation of empirically based educational/training modules to foster and guide these new types of working relationships. The target audience of these modules includes, but is not limited to, individual researchers conducting or developing plans for community-based mental health research, or institutions that can train researchers in conducting community-based research.

Phase 1 should include: (1) a summary review of the evidence on effective community engagement and development of a list of resource articles and case-studies; (2) developing an operationalized plan for the development of content for each of the community engagement modules (with input from researchers and targeted community populations), and designing for each module a format and presentation plan; (3) designing a plan to pilot and evaluate modules which includes the participation of NIMH supported researchers and (4) plans for updating and archiving research progress and innovation (including e-journals). The format for these modules is not limited and may be manual-based, web-based, or use a train the trainers model, or be a combination of strategies.

CURRICULAR NEEDS

A project may target one or several underserved populations. Examples of areas that the training modules could target include:

- Background/Preparation

-goals and importance of community participation

-defining the specific target community: demographics, history, etc.

-understanding the historic relationship between research institution and community

-planning for the time and personnel needed

-establishing inclusion values within the project and staff (assessment of attitudes)

- Beginning partnerships with communities

-identifying key stakeholders and key community informants (formal and “natural” leaders)

-deciding how and when to engage the community

-developing community advisory boards (authority, structure, function, duration)

-timing the steps of involvement

- Getting community input

-understanding cultural appropriateness and acceptability for the specific community

-conducting community needs assessments

-developing mutual or compatible goals

-ethical issues (i.e.: how does the community define them?)

-data and safety monitoring: issues from the community

- Sustaining the partnership

-maintaining an active community advisory board

-common problems/issues and how they might be addressed

-dealing with significant changes in the community or the research

-on-going communication between community and research

- Determining success of the partnership/Enhancing future successes

-determining “success” as defined by various sectors of the community and by research standards

-assessing strengths and weaknesses to improve future collaboration

-building knowledge about community-research collaboration: sharing experiences

The products created under this contract should, where appropriate, include consideration of the particular requirements and methods of specific research domains, that is: prevention research, treatment studies, and services research. The products also should include consideration of issues related to working with a population and with specific sub-groups of such populations (i.e.: adults, children, adolescents, families, elderly, etc.) As input from both mental health researchers and traditionally underserved communities is viewed as an essential component of the development of the modules, the contractor must show capability for working with both groups.

0204 Web-based Resource on Meeting the Mental Health Needs of Individuals with Neuropsychiatric and Neurodevelopmental Disorders

The purpose of this contract is to develop an interactive web-based resource for care providers (e.g., health care providers, community service providers, educators, vocational training, etc.) that: (1) can be used to assist in the identification of the mental health needs of individuals(and their families) with neuropsychiatric and neurodevelopmental disorders (e.g., autism spectrum disorders, Tourette’s syndrome, Fragile X syndrome) across the lifespan; (2) disseminate information about practice guidelines, evidence-based treatments and research based and validated model programs; and (3) provide information about available public and private funding for services. Information about public and private funding for services is best prepared by state as Medicaid may be the primary insurer of services. The information should include a description of the design of the Medicaid program (such as carve-out provisions, etc.) as well as key contact information to assist providers in navigating the reimbursement systems. Input from researchers, health care providers, community service providers, educators, vocational trainers/job coaches, families, and experts in financing services should be obtained in developing all aspects of this resource.

Neuropsychiatric disorders and neurodevelopmental disorders are syndromes in which a known or presumed neurological impairment affects the cognitive, emotional, and/or developmental presentation of an individual. Impairment may range from mild to severe, may affect specific skills or global functioning, and affect adaptive functioning in the home and community. Diagnosis and treatment planning are often multidisciplinary endeavors needing expertise from medical and mental health professionals. Risk for comorbid mental health disorders is high, but assessment and treatment of mental health functioning is complicated, and access to mental health care is often limited.

A web-based resource can provide up-to-date information to promote prevention and early detection of mental health disorders in individuals with developmental disabilities. The resource can be interactive and promote cross-disciplinary exchange of syndrome-specific information, disseminate information about evidence-based practices, facilitate new research activities to address gaps in the evidence base; and the financing of services from public and other resources.

Content areas may include:

State of the art screening and diagnostic procedures

Best practice guidelines with regard to diagnosis and treatment in special populations

Current knowledge about syndrome-specific risk for cognitive, emotional, and behavioral disturbances

Information about model programs

Links to other relevant web sites and other resources that are identified as credible sources of information

Insurance and financing information

The web site should be innovative in its use of appropriate web technology (e.g., creative/appropriate use of interactive forms, multimedia) as an educational tool for the intended audience. It is expected that technical and usability input will be obtained from experts

in the fields of mental and allied health care (social psychology, behavioral science, educational and clinical psychology, managed care providers), pediatrics, genetics, neurology, general medicine, financing and health services/health policy.

For Phase I the offeror may focus on one or more disorders or age groups. Particular attention should be paid to individuals who are in transitional phases (e.g., aging out of eligibility for services).

0205 Evaluating Mental Health Interventions and Services Research Protocols in Urban and Rural Communities: Empirically Based Ethics Training Modules

The ethics of mental health interventions and services research is a topic of national importance. Focus on this topic stems from various factors, including concerns relevant to persons with diverse vulnerabilities (e.g., cognitive impairment, comorbidity, language or cultural issues, limited resources, social supports, and/or access to treatment), the rapid development of new medications and evidence-based practices, the expansion of mental health research into non-traditional research settings (e.g., the community: schools, jails and prisons, etc.), the broadening of study inclusion criteria (suicidal individuals, pregnant and nursing women, children and other underserved populations) and recent recommendations of the President's National Bioethics Advisory Commission (NBAC): http://bioethics.georgetown.edu/nbac/). To meet new and evolving ethical standards for conducting mental health interventions and services research there is a critical need to develop empirically based ethics training modules to assure that research protocols are appropriately designed and reviewed. These ethics training modules need to be suitable to train a broad base of professionals involved in mental health services and interventions research including: persons reviewing and approving (e.g., IRBs) research designs; individuals designing and implementing research protocols; professionals participating in such studies and students/young investigators.

While there has been a focused effort to develop research and disseminate information about ethical issues in informed consent procedures, and this focus must continue, informed consent is only one of the central issues related to the overall ethical assessment of any given research protocol. There remains a need for a more developed and comprehensive definition of and education about a broader array of mental health research ethics issues. This could include ethical aspects of scientific design and review, subject recruitment, confidentiality, patient safety, incorporation of community factors, etc. Empirically based modules must be tailored to train targeted individuals about informed consent as well as these broader based aspects of research protocols.

An added challenge to improving the ethical standards of research protocols is the increasing complexity and scope of mental health interventions and services research (e.g., large public health oriented multi-site trials, services networks). The broad public health nature of current research designs frequently requires studies to be conducted across very different locations (rural and frontier, urban, suburban, ethnic community, etc.) rather than at a single university based settings. Research protocols must take into consideration various levels of risk to participants and consider issues related to treatment as usual (TAU) and treatment as usual may vary considerably between study sites. In studies that span urban and rural/frontier locations ethical issues related to stigma and confidentiality may be posed in different ways.

Typically services and intervention studies are conducted by persons (or teams of investigators) with various professional backgrounds and may include physicians, clinical psychologists, social workers, outreach workers, nurses, pharmacists, clinical epidemiologists, anthropologists, economists, statisticians, etc. Thus, proposed training modules must address ethical concerns and issues that may be specific to a variety of relevant disciplines, backgrounds, and study sites. However, it is clear that all participating members (not only the principal investigator, co-PI) of a study team must be trained in all aspects of the ethical design of research protocols.

The focus of this Phase I contract is to: (1) produce an annotated bibliography and a set of case-examples relevant to the evaluation of mental health services and interventions protocols from an ethics perspective (2) develop empirically based training materials and strategies to teach individual researchers and

members of research teams (including IRBs) representing diverse disciplines how to review and evaluate mental health services and intervention protocols from an ethics perspective; and (3) to develop a plan to pilot and refine these strategies and materials.

The target audience for these tools includes, but is not limited to: established individual researchers; junior investigators and individuals in research training programs; clinical practitioners who participate in research protocols; IRB members; and journal referees. Strategies and materials should be ecologically sound and tailored to the appropriate audiences. The format for these educational tools is not limited and may be in print, CD, video, and internet-based or be a combination of strategies. Particular attention must be given to the unique set of ethical issues encountered when the research protocol involves rural and frontier settings and to practical ways to update training materials and provide advanced/emerging information to individuals who have received initial training (this may include web-sites, e-journals etc.).

Recent research articles have highlighted the unique and challenging aspects of conducting research with the seriously mentally ill being treated in the public sector in rural and frontier communities. Proposals may choose to focus solely on developing empirically based ethics training modules for mental health interventions and services research protocols in rural and frontier areas and the delivery of such model training.

Fortney, J, Rost, K, Zhang, ML, Warren, J. *The impact of geographic accessibility on the intensity and quality of depression treatment.* MEDICAL CARE. 37: (9) 884-8493 SEP 1999.

Roberts, LW, Battalia J, Epstein, RS. *Fontier ethics: Mental health care needs and ethical dilemmas in rural communities.* PSYCHIATRIC SERVICES 50: (4) 497-503 APR 1999.

Rost, K, Owen, RR, Smith, J, Smith, GR. *Rural-urban differences in service use and course of illness in bipolar disorder.* JOURNAL of RURAL HEALTH. 14: (1) 36-43 WIN 1998.

Rost, K, Zhang, ML, Fortney, J, Smith J, and Smith GR. *Rural-urban differences in depression treatment and suicidality.* MEDICAL CARE. 36: (7) 1098-1107 JUL 1998.

ATTACHMENT N0. 1

PROPOSAL INTENT RESPONSE SHEET

Under NIMH SBIR Solicitation No. NIMH-02-SBIR-PhaseI

PLEASE REVIEW THE ATTACHED REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY APRIL 30, 2002 TO THE ADDRESS SHOWN BELOW. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

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National Institute of Mental Health
Contracts Management Branch, ORM
Attn: Alex Navas, Contract Specialist
6001 Executive Boulevard
Room 6107, MSC 9603
Bethesda, Maryland 20892-9603
Tel: 301-443-2696
Fax: 301-443-0501